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C. R. Bard, Inc. and
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14 **IN THE UNITED STATES DISTRICT COURT**
15 **FOR THE DISTRICT OF ARIZONA**

16 IN RE: Bard IVC Filters Products Liability
17 Litigation

No. 2:15-MD-02641-DGC

**DEFENDANTS C. R. BARD, INC.'S
AND BARD PERIPHERAL
VASCULAR, INC.'S REPLY IN
SUPPORT OF MOTION TO
EXCLUDE THE OPINIONS OF
THOMAS KINNEY, M.D., ANNE
CHRISTINE ROBERTS, M.D., AND
SANJEEVA KALVA, M.D.**

(Assigned to the Honorable David G.
Campbell)

(Oral Argument Requested)

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1 In their Response,¹ the Plaintiffs do not address many of Bard’s arguments and
 2 citations to authority. The Plaintiffs also accuse Bard of “selectively distort[ing] their
 3 [experts’] testimony as well as the relevant case law” (Pls. Resp. Br. (Doc. 7812), at 2),
 4 which Bard does not think is accurate. Finally, the Plaintiffs recast many of Bard’s
 5 arguments by inaccurately describing Bard’s positions and then citing portions of the
 6 record and case law that either are distinguishable or do not bear on the issues raised in
 7 Bard’s Motion. For these reasons, the Plaintiffs have not met their burden of proof for
 8 admissibility of the opinions of Drs. Kinney, Roberts, and Kalva that Bard moved to
 9 exclude.

10 **A. The Doctors’ Reliance on Rule 26 Reports of Other Experts Is Improper**
 11 **Under Rule 703 in this Case.**

12 In their careers as physicians and academics, Drs. Kinney, Roberts, and Kalva have
 13 never seen or relied on (1) opinions formed for litigation (i.e., the opinions of Drs.
 14 Kessler, Ritchie, and Betensky, which they cite throughout their Rule 26 Report), (2)
 15 internal company documents, and (3) internal company analyses. (Mot. (Doc. 7296), at 2-
 16 3.) As such, their reliance on this material in litigation is unreasonable and should not be
 17 permitted under Rule 703. *See, e.g., Weinstein & Berger, Weinstein’s Evidence Manual* §
 18 13.03[2][c] (2016) (“Since Rule 703 is concerned with the trustworthiness of the resulting
 19 opinions, the proponent of the expert must establish that experts other than the proposed
 20 witness would act upon the information relied upon, and would do so for purposes other
 21 than testifying in a lawsuit.” (citations omitted)). The Plaintiffs do not address Bard’s
 22 argument in their Response.

23 Instead, the Plaintiffs raise numerous issues that do not bear on the Rule 703
 24 analysis. First, they claim that Drs. Kinney, Roberts, and Kalva “directly sought [alleged

25 ¹ Plaintiffs filed a separate Omnibus Statement Of Law And Generally-Applicable
 26 Arguments In Opposition To Bard’s Motions To Exclude Plaintiffs’ Experts Under Rule
 27 702 And Daubert (Doc. 7799). Plaintiffs’ Omnibus Statement is not directed at any
 28 specific Daubert motion Bard filed. As such, Bard does not respond to the Omnibus
 Statement but instead will address any necessary issues in the context of its individual
 Daubert replies.

safety] information from Bard when they became concerned about the safety of the Recovery and G2 filters.” (Pls. Resp. Br., at 5, 6.) The Plaintiffs only cite testimony from Dr. Kinney, however, where he answered a question about how the Rule 26 Report was prepared (“We basically used the document by Dr. Kessler is what we did”) and he discussed performance characteristics of retrievable IVC filters in general, not Bard filters specifically. (Kinney Dep. Tr., at 73:23 to 75:19, excerpt attached as Exhibit A.) Second, the Plaintiffs also claim that “Dr. Kinney expected that the company would tell him what it knew,” (Resp. at 6), but the testimony cited is vague and was in the context of Dr. Kinney consulting for Bard. Third, the Plaintiffs argue that “Indisputably, the Experts—and the entire community of interventional radiologists—would have welcomed the information Bard produced in this litigation” But the Plaintiffs cite no testimony and no authority to support their assertion. *See, e.g., I.N.S. v. Phinpathya*, 464 U.S. 183, 188-89 n.6 (1983) (“Counsel’s unsupported assertions in respondent’s brief do not establish that respondent could satisfy [the applicable legal test].”).

Because the Plaintiffs neither address Bard’s argument nor raise arguments that bear on the Rule 703 analysis, the Court should exclude the doctors’ opinions premised on others’ opinions formed for litigation, internal documents, and internal analyses.

B. The Doctors’ Reliance on Rule 26 Reports of Other Experts Is Improper Under Rule 702 in this Case.

Whether an expert may rely on the findings of others turns on whether the relying expert conducted an independent evaluation of the evidence to allow him or her to reach reliable opinions under Rule 702. *See, e.g., In re ConAgra Foods, Inc.*, 302 F.R.D. 537, 556 (C.D. Cal. 2014) (“[A]n expert can appropriately rely on the opinions of others if other evidence supports his opinion and the record demonstrates that the expert conducted an independent evaluation of that evidence.”) (citations omitted); *Cholakyan v. Mercedes-Benz, USA, LLC*, 281 F.R.D. 534, 544 (C.D. Cal. 2012) (“an expert can appropriately rely on the opinions of others if other evidence supports his opinion and the record demonstrates that the expert conducted an independent evaluation of that evidence”).

The Plaintiffs cite several cases in their response briefing and “Omnibus Statement of Law” in which the experts satisfied the “independent evaluation” requirement to reach their opinions. *Jerpe v. Aerospatiale*, No. CIV. S-03-555 LKK/DAD, 2007 WL 1394969, at *6 (E.D. Cal. May 10, 2007) (finding that the expert at issue in a product liability action concerning a helicopter blade independently conducted a visual inspection of the blade; evaluated photographs, x-rays, and ultrasounds; and independently arrived at the same opinions as contained in another expert’s report); *Gray v. United States*, No 05cv1893 J(BLM), 2007 WL 4644736, at *8 (S.D. Cal. Mar. 17, 2007) (noting that the expert relied on numerous sources of information other than another expert’s report in forming her opinions).² These cases, however, stand in contrast to the approach that Drs. Kinney, Roberts, and Kalva took in arriving at their opinions. Nearly all of the “Opinions” section of their Rule 26 Report concerning Bard’s internal documents are derived directly from the reports of Drs. Kessler, Ritchie, and Betensky, not “thousands of pages of documents and testimony” or “their own published, peer-reviewed research and that of their colleagues.”³ In fact, throughout their entire 114-page Rule 26 Report, Bard could only find two internal company documents cited by Drs. Kinney, Roberts, and Kalva that were not discussed in other experts’ Rule 26 Reports, and principally were discussed in Dr. Kessler’s Report. These facts underscore Dr. Kinney’s repeated testimony that “The main source for my document was the Kessler report,” and not an independent evaluation of

² Although the Plaintiffs cite *In re Toyota Motor Corp. Unintended Acceleration Marketing, Sales Practices, and Products Liability Litigation*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013), repeatedly in their Omnibus Statement of Law and Response Brief, to argue that an “expert’s opinion was admissible because he reviewed other types of data, not solely other experts’ opinions,” (Omnibus Statement (Doc. 7799) at 7; Pls. Resp. Br., at 7), the issue of whether the expert properly relied on the other experts was not before that court. Rather, the defense challenged the admissibility of the opinion as unreliable because it was based solely on the plaintiff’s testimony, which the court pointed out was inaccurate. *In re Toyota*, 978 F. Supp. 2d at 1066. And *Mesfun v. Hagos*, No. CV 03-02182 MMM (RNBx), 2005 WL 5956612, at *18 (C.D. Cal. Feb. 16, 2005), concerns Rule 703, not Rule 702 as Bard argues here.

³ While the experts discuss medical literature and their view of the SIR Guidelines, the discussions are limited to their own sections of the report, and nothing in the report draws comparisons between the medical literature, SIR Guidelines, and Bard’s internal documents that are cited. Additionally, Bard is not challenging the admissibility of the experts’ opinions about the medical literature and SIR Guidelines.

1 other evidence that supports the opinions expressed in the Rule 26 Report. (Mot. at 3
 2 (quoting numerous other language throughout Dr. Kinney's deposition to the same
 3 effect).)

4 The Plaintiffs claim that "the record is clear that the Experts independently
 5 evaluated every source document cited in the reports of Drs. Kessler, Ritchie, and
 6 Betensky to ensure coherence with their analyses," and that Drs. Kinney, Roberts, and
 7 Kalva "carefully scrutinized the[se] experts' underlying data in developing their own
 8 opinions." (Resp. at 6, 7.) These assertions, however, appear to be inaccurate.

9 Dr. Kinney testified as follows:

10 Q. But as far as reviewing the underlying data cited by Dr. Ritchie, Dr.
 11 Betensky, and Dr. Kessler, am I correct that other than the specific documents
 12 that you were curious about when you were reviewing Dr. Kessler's report,⁴
 that you have not reviewed any other underlying data cited by either [sic] of
 those three reports?

13 MR. JOHNSON: Form.
 14 You can answer.

15 THE WITNESS: I would agree with that as a general statement, yes.

16 (Ex. E to Mot., 223:9-18.)

17 The Plaintiffs likewise claim that Dr. Kalva, who wrote only the last nine pages of
 18 the 114-page Rule 26 Report, "reviewed every document cited in the reports of Drs.
 19 Kessler, Betensky, and Ritchie." (Resp. at 8.) But this statement also appears to be
 20 inaccurate. Dr. Kalva testified that all of the documents that he reviewed were provided
 21 via DropBox (Kalva Dep. Tr., 165:12-21, attached as Exhibit B.) The DropBox folder
 22 that the experts received, however, only contained the documents cited on the "Facts and
 23

24 ⁴ Referring to Dr. Kinney's previous testimony that "if I had trouble reading one of
 25 Kessler's things, and I was looking for something to grasp or hard to read, I wanted to
 26 look and see, so I would pull that document up," and Dr. Kinney did not do this until three
 27 months after he signed his report. (Ex. A, Kinney Dep. Tr., 20:12 to 21:10; 95:22 to 96:4;
 28 96:9-12.) When writing the Rule 26 Report, however, he was given only a handful of
 documents (approximately 20, by his guess) via a DropBox folder, which "was back-up
 material. The main source for my document was the Kessler report." (*Id.*) Of the handful
 of documents that he received via DropBox, he did not read all of them. (*Id.* at 81:19 to
 82:7.)

1 Data Considered” list appended to the doctors’ Rule 26 Report. (Ex. A, Kinney Dep. Tr.,
2 82:17-20.) And the “Facts and Data Considered” list of the doctors’ Rule 26 Report lists
3 only 42 internal Bard documents, contrasted with approximately 650 internal Bard
4 documents cited in the Reports of Drs. Kessler, Ritchie, and Betensky. (Ex. G to Mot.)
5 Neither the Plaintiffs nor the doctors have identified any list of “facts or data considered
6 by the doctors in forming their opinions,” as required by Rule 26(a)(2)(B)(ii), beyond the
7 42 internal Bard documents on the “Facts and Data Considered” list in the doctors’ Rule
8 26 Report.

9 Finally, the Plaintiffs cite testimony of Dr. Roberts, which actually verifies that she
10 did not independently evaluate all of the data underlying Dr. Kessler’s report (“I did go
11 back and look at some of those memos and some of those references” (Resp. at 8.))
12 and which says nothing about the reports of Drs. Ritchie and Betensky. Dr. Roberts also
13 testified that she does not remember what data was available for her to “independently
14 review,” and that she assumed that Drs. Kessler, Ritchie, and Betensky used reliable data
15 and methodologies. (Roberts Dep. Tr., 244:16 to 245:18, July 7, 2017, excerpts attached as
16 Exhibit C.)

17 In sum, by their own admission, Drs. Kinney, Roberts, and Kalva did not
18 independently evaluate the evidence in arriving at their opinions concerning Bard’s
19 internal documents, but rather relied on the Rule 26 Reports of Drs. Kessler, Ritchie, and
20 Betensky. As such, all of their opinions derived from these reports should be excluded.

21 **C. The Plaintiffs Do Not Address Bard’s Argument that Summaries and**
22 **Editorials of Internal Documents and Deposition Testimony Are Unhelpful**

23 The Plaintiffs recast Drs. Kinney, Roberts, and Kalva’s Rule 26 Report as
24 “testimony about Bard’s internal documents [that] will provide a contextual and factual
25 foundation for their opinions as interventional radiologists with specialized knowledge of
26 IVC filters and how IVC filters are intended to function in the human body.” (Resp. at
27 11.) Undoubtedly, Drs. Kinney, Roberts, and Kalva can provide medical context about
28 IVC filter clinical studies, the IVC filter medical literature, and the human anatomy

1 relative to their practice as interventional radiologists—Bard is not challenging the
2 admissibility of such opinions. Rather, Bard is challenging opinions that simply
3 summarize documents and testimony (which were largely selected for them by Plaintiffs’
4 counsel⁵), followed by editorials from the doctors expressing their concern about the
5 documents and actions that Bard should have taken. The Plaintiffs do not address the
6 merits of this argument.

7 Consider a few of the many such examples from their Rule 26 Report. Paragraphs
8 144 through 148 summarize and quote numerous internal Bard documents about adverse
9 events. Drs. Kinney, Roberts, and Kalva opine, “[i]t is our opinion that this information
10 was important for physicians to know. This data raises safety concerns [We expect]
11 Bard would immediately recall and stop selling the Recovery Filter.” (Ex. G to Mot, at ¶
12 148.) Similarly, Paragraphs 152 through 160 summarize internal Bard documents about
13 adverse events, changes in the design specifications between the Recovery and G2 Filters,
14 and results of bench testing of the G2 Filter. Drs. Kinney, Roberts, and Kalva then opine,
15 “In our opinion, this is concerning” (*Id.* at ¶ 160.) These examples reflect the general
16 formula that Drs. Kinney, Roberts, and Kalva used to write a large portion of their report:
17 summarize and quote internal Bard documents, opine that the documents are concerning,
18 and then opine that Bard should have done something differently. But the doctors never
19 cite to any sources of authority to support their opinions, they give no indication that their
20 opinions have been tested or peer reviewed, their opinions have no known rate of error,
21 they have not been published, and the physicians have not identified their view as
22 generally accepted in the medical community. Such opinions amount to unhelpful

23 ⁵ The Plaintiffs spend a portion of their argument claiming that the physicians “decided
24 which documents to include as references in their report,” which appears to be accurate,
25 but does not address the fact that the Plaintiffs’ lawyers selected the documents that Drs.
26 Kinney, Roberts, and Kalva received. As Dr. Kinney testified, “I didn’t specifically
27 request them, but they were in this – in Kessler’s report,” which was prepared using
28 documents that the Plaintiffs’ lawyers selected and summarized for Dr. Kessler. (Ex. A,
Kinney Dep. Tr., 82:21 to 83:10.) The Plaintiffs challenge Bard to put these lawyer-
selected documents into context with the roughly 1.5 million documents produced in the
litigation, but their argument has no bearing on whether Drs. Kinney, Roberts, and Kalva
should be permitted to quote/summarize and editorialize about Bard’s documents.

1 summaries of an infinitesimal number of documents produced in the litigation, along with
2 the doctors' *ipse dixit* opinions about the documents. *Daubert v. Merrell Dow Pharms.,*
3 *Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) ("We've been
4 presented with only the experts' qualifications, their conclusions and their assurances of
5 reliability. Under *Daubert*, that's not enough.").

6 The case law that the Plaintiffs cite in their Omnibus Statement of Law and
7 Response brief does not support admissibility of the doctors' quotations, summaries, and
8 personal opinions. Rather, the Plaintiffs' cases support Bard's argument that such
9 material should be excluded, as do the many cases that Bard cited in its Motion (none of
10 which the Plaintiffs addressed in their Response or their Omnibus Statement of Law). For
11 example, in *Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3
12 (D. Ariz. Mar. 30, 2012), Judge Martone found in a pain pump product liability action that
13 the plaintiffs' regulatory expert "will generally not be allowed to simply read documents
14 that the jurors may read and interpret for themselves," but rather must "provide some
15 analysis, opinion, or expertise when testifying about the regulatory process and history of
16 pain pumps." Thus, the expert could not simply recite documents to the jury, was "not
17 permitted to give an opinion based on her 'subjective belief or unsupported speculation,'" and
18 had to offer "objective standards." *Id.* (quoting *Daubert v. Merrell Dow Pharms., Inc.*,
19 509 U.S. 579, 590 (1993)). Judge Martone concluded, much like the quotations/
20 summaries and personal opinions here, that anything "grounded on nothing more than her
21 personal views will be excluded." *Id.*; *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-
22 FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) (finding that regulatory experts
23 would not be permitted to recite or summarize documents, but must provide analysis,
24 opinion, or expertise in the regulatory process; and that they may not offer opinions about
25 defendants' knowledge or state of mind).⁶

26 ⁶ *United States v. Newmont USA Ltd.*, No. CV-05-020-JLQ, 2007 WL 4856859, at *3
27 (E.D. Wash. Nov. 16, 2007), which the Plaintiffs also cite, is inapposite to the facts in the
28 Bard IVC filter litigation. There, the court found that when the events at issue in the
lawsuit took place three decades earlier, and where the fact finder must necessarily rely on
testimonial narratives, the court permitted an expert historian to testify about nearly thirty

1 Finally, the Plaintiffs’ assertion that “narrative” objections should be reserved for
 2 trial does not address Bard’s *Daubert* argument that personal summaries and editorials
 3 (i.e., opinions grounded on nothing more than personal views, which fail to meet any of
 4 the *Daubert* factors) about lawyer-selected documents are unhelpful to the jury and should
 5 be excluded. As illustrated by the many cases that Bard cited in footnote 3 of its Motion,
 6 these issues are routinely decided at the *Daubert* stage, although Bard agrees that the
 7 parties should be able to raise objections at trial to the extent that experts’ testimony runs
 8 afoul of the Court’s *Daubert* rulings.

9 For each of these reasons, the Court should preclude Drs. Kinney, Roberts, and
 10 Kalva from summarizing and editorializing about deposition testimony and internal Bard
 11 documents based on nothing more than their personal opinions.

12 **D. Drs. Kinney, Roberts, and Kalva’s Opinions about the “Reasonable**
 13 **Expectations” of Physicians and How a “Reasonable Physician” Would**
 14 **Think and Act Regarding Information Are Inadmissible.**

15 In its Motion, Bard argued that the opinions of Drs. Kinney, Roberts, and Kalva
 16 about the “reasonable expectations” of physicians and how a “reasonable physician”
 17 would think and act on information are inadmissible because they are not grounded in any
 18 reliable sources of authority and they do not satisfy any of the *Daubert* factors (i.e., they
 19 have not been tested or peer reviewed, they have no known rate of error, they have not
 20 been published, and the physicians have not identified their view as generally accepted in
 21 the medical community). In support of its argument, Bard cited numerous prescription
 22 product liability cases that excluded expert opinions about what other physicians think and
 23 how other physicians should, or would have, acted. The Plaintiffs, however, do not
 24 address any of the cases that Bard cited, nor do they address the fact that Drs. Kinney,
 25 Roberts, and Kalva’s opinions do not satisfy any of the *Daubert* factors.

26 Rather, the Plaintiffs argue that the informed consent process, and a practice
 27 guideline about informed consent, provide a sufficient basis to admit Drs. Kinney,

28 years’ worth of documentary evidence expressing different historical understandings of
 events and a conflicting historical record.

1 Roberts, and Kalva's opinions. As the party bearing the burden of proof, however, the
 2 Plaintiffs have not identified a single case where opinions about "reasonable expectations"
 3 of a physician and how a "reasonable physician" would act in an informed consent context
 4 were admitted in a product liability case.⁷ Moreover, informed consent is not an element
 5 of any claim or defense, as it is strictly a medical malpractice concept, the Plaintiffs have
 6 cited nothing to the contrary, and the doctors' opinions therefore do not "fit" the case.
 7 Finally, the *ACR-SIR-SIR-SPR Practice Parameter on Informed Consent for Image-*
 8 *Guided Procedures*, attached hereto as Exhibit D, that Drs. Kinney, Roberts, and Kalva
 9 identify in their Report says nothing about the information required to satisfy informed
 10 consent. Instead, the *Practice Parameters* say that they "are not intended, nor should they
 11 be used, to establish a legal standard of care." (*Id.* at 1.) When asked at her deposition
 12 whether she had any written authority supporting the doctors' opinion that certain
 13 information from Bard was required to satisfy the informed consent *Practice Parameters*,
 14 Dr. Roberts cited no authority and provided a personal opinion. (Ex. C, Roberts Dep. Tr.,
 15 at 296:6-19.) "Q. That's the Dr. Roberts' standard, correct? A. Well, we'll have to get
 16 100 people in a room and find out." (*Id.* at 296:21-25.) As discussed in Bard's Motion,
 17 these are classic, *ipse dixit*, and inadmissible opinions.

18 The Plaintiffs also cite several cases from the Ninth Circuit, but the cases do not
 19 bear on whether experts in product liability litigation can offer opinions about "reasonable
 20 expectations" or how "reasonable physicians" think and act in an informed consent
 21 context.⁸ Finally, the Plaintiffs cite to testimony of several Bard fact and expert

22 ⁷ The Plaintiffs' footnote that Bard relies on the "learned intermediary" doctrine as an
 23 affirmative defense has no bearing on the admissibility of the opinions of Drs. Kinney,
 24 Roberts, and Kalva. Indeed, other than in the Fifth Circuit (which does not govern the law
 25 of any of the bellwether cases), no other jurisdiction accepts an objective-evidence
 26 standard concerning the learned intermediary doctrine. *See, e.g., Fields v. Eli Lilly & Co.*,
 116 F. Supp. 3d 1295, 1306 (M.D. Ala. 2015) (citing cases). Rather, other jurisdictions
 require subjective evidence of how the treating physician would have responded to certain
 information. *Id.*

27 ⁸ *Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010) (finding that an expert's opinion
 28 may be admitted when the expert used "the ordinary methodology of evidence-based
 medicine" to develop his opinion in contrast to the lack of any identified methodology
 proffered in this case by Drs. Kinney, Roberts, and Kalva to support their opinions about

witnesses. (Pls. Resp. Br., at 14-15.) Much of this testimony, however, is taken out of context; Bard is not offering any of the testimony as expert opinions in this litigation; and the testimony does not change the *ipse dixit* nature of Drs. Kinney, Roberts, and Kalva's opinions.

For each of these reasons, Drs. Kinney, Roberts, and Kalva should not be permitted to opine about the "reasonable expectations" of physicians and how a "reasonable physician" would think and act.

E. Drs. Kinney, Roberts, and Kalva Are Unqualified To Offer Opinions about IVC Filter Engineering and the Suitability of Bard's Bench Testing of Its IVC Filters.

The fact that "for decades, the Experts have inserted IVC filters in countless patients, have removed filters that tilted, migrated, perforated and/or fractured, and published numerous papers describing complications with these devices" (Pls. Resp. Br., at 15) does not qualify the doctors to offer opinions about the proper or required testing that Bard should have undertaken with its IVC filters. Bard cited numerous cases to this effect (Mot. at 12-13), none of which the Plaintiffs addressed in their Response.

Other than the fact that Dr. Kinney has a Master's degree in mechanical engineering that he received in 1979 and for a brief period in the early 1980s helped with design work for angioplasty balloons, vascular claims, and a cardiopulgia jacket for use during open heart surgery (*see* Mot. at 11), the Plaintiffs have not identified anything in the last 30 years of his career that would qualify him to give the engineering and bench

"reasonable expectations of physicians" and how a "reasonable physician" would think and act); *United States v. Hankey*, 203 F.3d 1160 (9th Cir. 2000) (finding that a police officer with years of experience working undercover with gang members amounted to expertise not developed through the scientific method, which stands in contrast to the scientific and medical issues in this litigation); *Harbeson v. Parke Davis, Inc.*, 746 F.2d 517 (9th Cir. 1984) (providing a general statement of Washington state's informed consent doctrine in a medical malpractice case, not a product liability case); *Saint Alphonsus Med. Ctr. - Nampa, Inc. v. St. Luke's Health Sys., Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL 407446 (D. Idaho Jan. 24, 2014) (antitrust case involving acquisition of a group of healthcare providers in a given geographic area where the expert testified that "interoperability is both a business imperative as well as national policy" in the context of integrated medicine, and having nothing to do with what a "reasonable physician" thinks or does).

1 testing opinions that he offers. Dr. Kinney's work with Bard concerning IVC filters
 2 related to placing and removing the filters in animals and providing clinical input about
 3 the use of filters. (Pls. Resp. at 15; Ex. A, Kinney Dep. Tr., 196:12; 313:18-21.) And Dr.
 4 Kinney's work as Chair of data safety monitoring boards for clinical trials involving IVC
 5 filters concern clinical aspects of filters, not evaluations of engineering and bench tests.
 6 (Pls. Resp. at 15-16.)

7 Likewise, the Plaintiffs have not identified anything in the background of Dr.
 8 Roberts related to bench testing and engineering issues concerning IVC filters. Rather,
 9 they point to clinical work that she has done with IVC filters over the years, as well as
 10 study design and FDA panel work concerning evaluation of clinical data about devices.
 11 (Resp. at 6.)

12 And the Plaintiffs have not identified anything in the background of Dr. Kalva
 13 related to bench testing and engineering issues concerning IVC filters beyond a vague
 14 reference to "developing a patent for an IVC filter design" with no detail about Dr.
 15 Kalva's role in the patent or design. (Pls. Resp. Br., at 16.)

16 The Plaintiffs cite no case law where a practicing physician who works extensively
 17 with the device at issue is qualified to provide opinions on engineering issues and bench
 18 testing issues solely by virtue of the physician's clinical experience with the device. On
 19 the other hand, Bard has cited numerous, unrebutted cases where courts found that
 20 practicing physicians with extensive experience with the products at issue were not
 21 qualified to offer engineering and testing opinions.

22 Finally, regardless of qualifications, Drs. Kinney, Roberts, and Kalva's opinions
 23 about engineering and bench testing fall under the umbrella of Section C, above, because
 24 the experts provide no citations to sources of authority for their opinions, they give no
 25 indication that their opinions have been tested or peer reviewed, their opinions have no
 26 known rate of error, they have not been published, and the physicians have not identified
 27 their view as generally accepted in the medical community. Thus, their engineering and
 28 bench testing opinions are nothing more than *ipse dixit* personal opinions that should be

1 excluded.

2 **Conclusion**

3 The Plaintiffs have not met their burden of proof that the sweeping opinions of Drs.
4 Kinney, Roberts, and Kalva should be admitted. Accordingly, the Court should limit the
5 opinions of Drs. Kinney, Roberts, and Kalva to their proper areas of expertise concerning
6 their clinical experience with IVC filters and their interpretation of the medical literature.

7 RESPECTFULLY SUBMITTED this 18th day of October, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of October 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.
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